FDA Commissioner's Fellowship Program

Class of 2014

FDA Commissioner's Fellowship Program

2014 Fellows

FDA Commissioner's Fellowship Program

2014 Preceptors

FDA Commissioner's Fellowship Program

2014 Preceptors and Fellows Projects listed by Regulatory Science Priority Area

Modernize Toxicology to Enhance Product Safety – 3

- Darrel R. Abernethy (Fellow: Shadia Zaman)
- Mugimane Manjanatha (Fellow: Todd Townsend)
- Yongbin Zhang (Fellow: Jia Yao)

Ensure FDA Readiness to Evaluate Innovative Emerging Technologies - 6

- Christine Karbiwnyk (Fellow: Geoffrey Kilili)
- Sean Linden (Fellow: Yasith Nanaykkara)
- Paul M. Morin (Fellow: Xia Xu)
- Brendan O'Leary (Fellow: Peter Tobin)
- Steven Oh (Fellow: Laura Ricles)
- Irshad Sulaiman (Fellow: Mohd Kabir)

Harness Diverse Data through Information Sciences to Improve Health Outcomes - 4

- Nicolette Borek (Fellow: Yu-Ching Cheng)
- Suzanne Hill (Fellow: Catherine McCollum)
- Ram Tiwari (Fellow: Yu-Yi Hsu)
- Donna Williams (Fellow: Silvia Secelean)

Implement a New Prevention-Focused Food Safety System to Protect Public Health - 1

- Peter Evans (Fellow: Eric Stevens)

Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health and Security - 1

- Marli Azevedo (Fellow: Sudhakar Agnihothram)

FDA Commissioner's Fellowship Program

2014 Preceptors and Fellows by Center

CBER	
Preceptors	**Fellows**
Steven Oh	Laura Ricles
Zuben Sauna	Wojciech Jankowski

CDER	
Preceptors	**Fellows**
Darrell Abernethy	Shadia Zaman
Ram Tiwari	Yu-Yi Hsu

CDRH	
Preceptor	**Fellow**
Brendan O'Leary	Peter Tobin

CFSAN	
Preceptors	**Fellows**
Peter Evans	Eric Stevens
Suzanne Hill	Catherine McCollum

CTP	
Preceptor	**Fellow**
Nicolette Borek	Yu-Ching Cheng

NCTR	
Preceptors	**Fellows**
Marli Azevedo	Sudhakar Agnihothram
Mugimane Manjanatha	Todd Andrew Townsend
Yongbin Zhang	Jia Yao

ORA	
Preceoptors	**Fellows**
Christine Karbiwnyk	Geoffrey Kilili
Sean W. Linder	Yasith Nanayakkara
Paul M. Morin	Xia Xu
Irshad Sulaiman	Mohd Shahjahan Kabir
Donna Williams-Hill	Silvia Secelean

FDA Commissioner's Fellowship Program

2014 Fellows

Sudhakar Agnihothram, Ph.D.

National Center for Toxicological Research (NCTR)

Division of Microbiology

Preceptor: Marli Azevedo, M.S., Ph.D.

Scientific & Professional Background

1996-2000 Bachelors of Pharmacy, The Tamilnadu Dr. M.G.R. Medical University, India.
2000-2002 Masters in Biotechnology, The Birla Institute of Technology and Sciences, Pilani, India.
2003- 2008 Ph.D. Integrated Microbiology and Biochemistry, The University of Montana, MT, USA.
2009-2014 Postdoctoral Fellow, The University of North Carolina at Chapel Hill, NC, USA.

Research Interests

Dr. Agnihothram`s postdoctoral research in the laboratory of Dr. Ralph Baric at UNC focused developing medical countermeasures including vaccines, therapeutics and diagnostics against high priority viral pathogens including Severe Acute Respiratory Coronavirus (SARS-CoV), Middle Eastern Respiratory Syndrome Coronavirus (MERS-CoV) and Influenza viruses, all of which pose threat to the nation from the public health and biodefense perspectives. Dr. Agnihothram was involved in the development of first line of therapeutic monoclonal antibodies and vaccines targeting MERS-CoV, and also in developing the first mouse model for studying MERS-CoV. His graduate research with Dr. Jack Nunberg focused on developing drugs for hemorrhagic fever causing arenaviruses. Dr. Agnihothram`s undergraduate research focused on identifying the pharmacological activities of several antimicrobial drugs using rat models of disease.

CFP Project Summary

Project Title: *Evaluating Changes in Host Transcriptome and Cellular Metabolism caused by exposure to Nanoparticles during Coronavirus and Norovirus infection as models of Enteric and Respiratory exposure.*

FDA Regulatory Science Priority Area: Facilitate Development of Medical Countermeasures to Protect Against Threats to U.S. and Global Health and Security

Nanoparticles (NPs) are used as drug delivery vehicles, as vaccine adjuvants, and in bio imaging and medical devices. There has also been a rapid increase in the use of nanomaterials in food, cosmetic and beverage industry. While the controlled use of NPs provide unparalleled benefits in the pharmaceutical and consumer product sectors, accidental exposure to increased dosage of the NPs including Silica, Zinc, and Titanium Dioxide result in enhanced inflammatory responses causing damage to lung and intestinal physiology, respectively. With emergence of novel coronaviruses and noroviruses in humans, high dose exposure of nanoparticles might exacerbate virus replication and/or the inflammatory responses in infected individuals. The overall objective of this proposal is to measure the changes in host transcriptome, cellular metabolism and virus replication upon exposure to nanoparticles in cells infected with coronaviruses and noroviruses as models for respiratory and enteric exposure. The project outcomes will facilitate development of diagnostics to detect biomarkers for NP toxicity in virus-infected individuals.

Yu-Ching Cheng, Ph.D.

Center for Tobacco Products (CTP)

Office of Science

Preceptor: Nicolette Borek, Ph.D

Scientific & Professional Background

2012-2014	Supervisory Research Health Scientist, Department of Veterans Affairs Maryland Health Care System
2013-2014	Assistant Professor, Department of Medicine and Epidemiology & Public Health, University of Maryland, Baltimore
2010-2013	Instructor, Department of Medicine, University of Maryland, Baltimore
2008-2010	Postdoctoral Fellow, Division of Endocrinology, Diabetes and Nutrition, Department of Medicine, University of Maryland, Baltimore
2008	Ph.D., Epidemiology, Johns Hopkins Bloomberg School of Public Health
2003	M.S., Epidemiology, National Taiwan University
2001	B.S., Zoology, National Taiwan University

Research Interests

Trained as an epidemiologist, Yu-Ching is interested in utilizing epidemiologic designs and statistical methods to identify genetic and non-genetic factors that predispose individuals to diseases. Her previous research focused on stroke, cardiovascular diseases and related comorbidities. As a FDA Commissioner's Fellow, she hopes to apply her expertise in epidemiology to ongoing FDA projects in areas related to tobacco product regulation.

CFP Project Summary

Project Title: *Assessing patterns of tobacco product use among US adults: descriptive findings from the Population Assessment of Tobacco and Health (PATH) study*

FDA Regulatory Science Priority Area: Harness Diverse Data through Information Sciences to Improve Health Outcomes

The PATH Study is a collaborative effort by the Center for Tobacco Products, FDA and the National Institute on Drug Abuse, NIH to monitor and assess tobacco product use, attitudes, biomarkers and health outcomes. A nationally representative sample of approximately 46,000 youth, young adults and adults aged 12 years and over are participating in the study. The sample includes current,

former, and never users of tobacco products. The goal of my project is to characterize the pattern of use for various tobacco products using the national-representative baseline data from the PATH study. The findings from this project will advance our understanding of the diversity of tobacco products in the U.S. and help inform FDA's regulatory actions related to tobacco products.

Yu-Yi Hsu, Ph. D.

Center for Drug Evaluation and Research (CDER)

Preceptor: Ram Tiwari, Ph.D.

Scientific & Professional Background

2013 Ph.D. Statistics, Iowa State University, Ames, IA

2000 M.S. Statistics, National Central University, Taiwan

1999 B.S. Mathematics, National Central University, Taiwan

Research Interests

Dr. Hsu's research interests include Bayesian methods, missing data analysis, and clinical data analysis. Her PhD dissertation focused on reducing parameter estimation bias for data with missing values using simulation extrapolation (SIMEX). The SIMEX method for missing data is a general simulation-based method that can be used to adjust bias for a variety of statistics by incorporating the missing data mechanism.

CFP Project Summary

Project Title: *Bayesian approaches to subgroup analysis*

FDA Regulatory Science Priority Area: Harness Diverse Data through Information Sciences to Improve Health Outcomes

Description:

In a clinical study, the study population may be partitioned into subgroups by observable group factors, for example, genotypes, age groups, life styles, or regions in a multi-regional clinical trial. Researchers are interested in making inferences about the treatment effect on both the whole population as well as for each individual subgroup. One difficulty of traditional methods is that the sample size of each subgroup is usually much smaller than the full study which is designed to reach certain statistical power. Additionally, when hypothesis tests performed on each subgroup, there rises concern of multiplicity. This project will explore the use of Bayesian methods on subgroup analysis.

Wojciech Jankowski, Ph.D

Center for Biologics Evaluation and Research (CBER)

Preceptor: Zuben E. Sauna, Ph.D

Scientific & Professional Background

2014 Postdoctoral Fellow, Center for Advanced Biotechnology and Medicine, Rutgers, NJ

2012-2014 Postdoctoral Fellow, Center for Integrative Proteomics Research, Rutgers, NJ

2012 Ph.D. Structural Biology, Rutgers, NJ

2006 M.S. Biotechnology, Warsaw University of Technology

Research Interests

As a biochemist and biophysicist with a strong background in structural biology and bioinformatics, Wojciech is especially interested in biological questions with particular emphasis on the biochemistry of biomolecules. His previous research focused on investigating the properties of complex biological systems including cell signaling and oncogenes. At FDA, he will apply his academic background to evaluate recent challenges in evaluation of therapeutic proteins during drug development and licensure.

CFP Project Summary

Project Title: *Development and evaluation of novel strategies for characterizing high-order therapeutic protein structure during drug development and manufacture*

FDA Regulatory Science Priority Ares: Support New Approaches to Improve Product Manufacturing and Quality & Ensure FDA Readiness to Evaluate Innovative Emerging Technologies

The development of neutralizing anti-drug antibodies (ADAs) to therapeutic proteins (immunogenicity) is an important issue that can be influenced by many factors. That includes patients and disease related factors or product related risk factors. Even subtle changes in the conformation of a protein can have a profound effect with respect to immunogenicity. There however remains a significant gap in analytical techniques that can be used for monitoring the tertiary and quaternary structures of proteins during drug development and manufacture. Finding solutions for this unmet need has gained increased urgency in recent years as regulators in both Europe and the US now have pathways for the development of biosimilars. A cornerstone of any program to develop a biosimilars program is the availability of reliable techniques to compare the conformations of innovator proteins and their biosimilars. There is also an emerging trend to develop bioengineered “bio-betters” and to alter the primary sequence to make proteins less immunogenic. All these changes have potential structural consequences. This project aims to develop and evaluate methods to monitor and compare the conformations of therapeutic proteins which can be used in the solution phase and easily and inexpensively used during drug development and routinely during manufacture.

Mohd Shahjahan Kabir, M.Sc., Ph.D.

Office of Regulatory Affairs (ORA)

Microbiological Sciences Branch

Southeast Regional Laboratory

Preceptor: Irshad Sulaiman, M.Sc., M.Phil, Ph.D.

Scientific & Professional Background

2011-2014	IRTA Fellow, National Institute of Health (NIH), National, Institute on Drug Abuse (NIDA), USA
2005-2011	Ph.D. in Synthetic Organic and Medicinal Chemistry, University of Wisconsin Milwaukee, USA
2001-2004	M.Sc. Student in Synthetic Organic Chemistry and Chemical Biology University of Saskatchewan, Canada
1994-1997	M.Sc. Synthetic Organic Chemistry, Jahangirnagar University, Dhaka, Bangladesh
1990-1994	B.Sc. (Honors) in Chemistry Jahangirnagar University, Dhaka, Bangladesh

Research Interests

Kabir is a trained experimental and investigative translational medicinal chemist. His graduate research involved on development of drug leads to treat bacterial pathogens, including drug resistant *M. tuberculosis,* MRSA, VRE and anthrax. His post-doctoral research at NIH/NIDA focused on the design and synthesis of functionalized phenylmorphans as high affinity ligands selective for opioid receptors. Currently, Kabir is involved in developing rapid diagnostic methods for the detection of *Bacillus* from food.

CFP Project Summary

Project Title: *Development of molecular diagnostic method that can rapidly identify Bacillus cereus and related species from food and environmental samples*

FDA Regulatory Scientific Priority Area and Summary: Ensure FDA Readiness to Evaluate Innovative Emerging Technologies

Bacillus cereus is an aerobic spore-forming bacterium that can infect raw and processed foods and cause foodborne illness in humans. *Bacillus thuringiensis* is a closely related species, known as biological insecticide, and has also been linked to human gastroenteritis illness. Currently, this agency follows conventional microbiologic protocols for its detection that involve several days to weeks to complete the analysis. Hence, in the proposed project, attempts will be made to develop a DNA based molecular method that can detect and differentiate *Bacillus cereus* and its closely related species from food and other sources. In addition, MALDI-TOF-MS platform will also be evaluated and validated for their rapid high-throughput diagnosis as the analysis can be completed within few hours with low cost and no long enrichment process. These novel tools may be used for rapid detection and species-identification of *Bacillus cereus* and related isolates recovered from food, outbreak, sporadic cases, routine surveillance, and the environmental samples of public health importance.

Geoffrey K. Kilili (Ph.D)

Office of Regulatory Affairs (ORA)
Winchester Engineering Analytical Center (WEAC)
Preceptor: Christine M. Karbiwnyk (Ph.D.)

Scientific & Professional Background

1995:	BS University of Nairobi, Kenya
2001:	M.S Biotechnology Mediterranean agronomic institute of chania, Greece.
2010:	Ph.D. Tufts University Boston, MA.
2010-2012:	Postdoctoral fellow Purdue University W. Lafayette, IN.
2012-2013:	HHMI Teaching Postdoctoral fellow, College of Wooster, Wooster, OH.
2013-2014:	UNCF/MERCK Postdoctoral fellow, National Institute of Health, Bethesda, MD

Research interest

My current research interests are focused on understanding the molecular and biochemical mechanisms that govern host-pathogen interactions, identification and application of molecular biomarkers of microbial pathogenesis in discovery and development of molecular tools for microbial detection, biosensors, therapeutics and diagnostics.

CFP Project Summary

Project Title: *Application of Aptamer technology in the rapid detection, capture and concentration of food-borne pathogens from complex sample matrices.*

FDA Regulatory Science Priority Area: Ensure FDA Readiness to Evaluate Innovative Emerging Technologies.

To prevent food poisoning, fast and accurate detection of foodborne pathogens is required. Rapid end point detection methods such as the polymerase chain reaction (PCR) and mass spectrometry (MS) are readily available. However, effective techniques for the rapid capture and concentration of pathogens from complex sample matrices are largely missing. Although the use of monoclonal antibodies is effective, antibodies are expensive, unstable and often exhibit batch to batch variability. Aptamers have recently emerged as an alternative molecular recognition element. Like antibodies, aptamers are simple molecular probes but bind their targets with higher specificity, selectivity and affinity. Importantly, unlike antibodies, their chemical synthesis is cheap, quick and easily scalable, are easy to chemically modify, have low batch to batch variability and are highly stable even in non-physiological conditions. To date, highly specific aptamers for the four major foodborne pathogens in U.S.A, *E. coli* O157:H7*, S. typhimurium, L. monocytogenes and C. jejuni* have been reported. Unfortunately, virtually all of these studies used purified antigens or laboratory bacteria stocks as ligands. Thus, disappointingly, the effectiveness and applicability of these aptamers and by extension, the aptamer based technology in the direct detection of pathogens in contaminated complex sample matrices is still unknown. The goal of this study is to develop a MS-coupled aptamer based rapid assay for the direct capture and identification of foodborne pathogens from complex sample matrices.

Catherine McCollum, Ph.D.

Office of Food Additive Safety (OFAS)

Center for Food Safety and Applied Nutrition (CFSAN)

Preceptor: Suzanne Hill

Scientific & Professional Background

2010-2014	Adjunct Chemistry Professor, Houston Baptist University, Houston, TX
2009-2014	Research Associate II, University of Houston, Houston, TX
2007-2009	Collaborative Project Manager, Rice University, Houston, TX
2008	Ph.D. Biochemistry and Cell Biology, Rice University, Houston, TX
2000	B.S. Biology and Chemistry, Houston Baptist University, Houston, TX

Research Interests

With a background in Development Biology, Catherine's research interests have focused on investigating the toxicological effects of environmental pollutants on embryonic development, using zebrafish as a model organism. Her previous work involved studying the adverse effects of arsenic and other chemicals, primarily pesticides, on vascular development, establishing zebrafish as an obesogen screening model using halogenated bisphenol A compounds, as well as examining the teratogenicity of various drugs and food/cosmetic additives.

CFP Project Summary

Project Title: *A Scientifically Based Guidance to Facilitate Efficiency of Environmental Reviews of Food Contact Notifications involving Antimicrobial Compounds*

FDA Regulatory Science Priority Area: Harness Data through Information Sciences to Improve Health Outcome

The National Environmental Policy Act (NEPA) of 1969, which was enacted into law on January 1, 1970, establishes a procedure by which all major federal agencies are held responsible to deliberate environ mental impacts when reviewing proposed actions (42 USC § 4321). The Food Contact Notification (FCN) program (21 CFR §170.100) was established within the Office of Food Additive Safety (OFAS) of the Center for Food Safety and Applied Nutrition (CFSAN) by the Food and Drug Administration Modernization Act (FDAMA) in 1997, whereby applications are submitted by industry for novel use of food contact substances (FCSs) and reviewed by FDA. FCSs are "any substance(s) intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have a technical effect in such food" (21 CFR §170.3). In other words, FCSs are substances that come in contact with food, or constituents that modifies food packaging materials of food contact articles. OFAS has reviewed over 1,500 FCNs as of date, many of which involve antimicrobial agents. Antimicrobial agents are used by food industry for preservation purposes to inhibit bacterial growth and pathogenic microorganisms. The environmental review process of an FCN entails a close evaluation of intended use of the proposed FCS and use levels, as well as its fate in the environment. Based on a survey of historical FCN submissions, there is a high volume of common deficiencies and inconsistencies. To ensure compliance with NEPA, the goal is to prepare and publish a scientifically based guidance that incorporates current approaches and flexibility to adjust to new regulations and studies, provide for consistent internal reviews, and increase quality of submission materials from notifiers as well as improve the analysis of impact from antimicrobial agents.

Yasith S. Nanayakkara, Ph.D.

Office of Regulatory Affairs (ORA)

Arkansas Regional Laboratory

Preceptor: Sean Linder, Ph.D.

Scientific & Professional Background

Scientist II: ALCON-Novartis Fort Worth TX	2013-2014
Research Scientist: AZYP LLC Arlington TX	2011-2013
Postdoctoral Research Associate: University of Texas at Arlington	2010-2011
PhD: University of Texas at Arlington, Arlington TX	2005-2010
BS: University of Peradeniya, Sri Lanka	1999-2003

Research Interests

Dr. Nanayakkara focuses on developing new methodologies and devices to identify and quantify regulated substances in food and drugs in a fast and efficient manner. Prior to joining the FDA, he was involved in analytical method validations and instrument qualification at ALCON. Before that, at AZYP he developed new chiral stationary phases (packing materials) for HPLC and a computer model to predict separation abilities of chiral molecules. Also, he was involved in separations of chiral compounds using HPLC. Earlier, at UT-Arlington he worked on number of diverse projects: (1) development of a new type of analytical detector and tunable liquid RC filler (2) method development for small molecules separations using HPLC (3) studied feasibility of ionic liquids in digital microfluidic devices.

CFP Project Summary

Project Title: *Use of metal nanoparticles with Surface Enhanced Raman Spectroscopy (SERS) for qualitative and quantitative analysis of contaminants within FDA regulated products.*

FDA Regulatory Science Priority Area: Ensure FDA Readiness to Evaluate Innovative Emerging Technologies.

Even with advanced technologies, the FDA faces challenges in the rapid identification and quantification of chemical contaminants and adulterants within products that it regulates. One example is histamine, which can be produced by certain species of fish. In this CFP project Yasith will focus on developing new methods to identify and quantify histamine & other targeted chemical contaminants using metal nanoparticles with Surface Enhanced Raman Spectroscopy (SERS). Raman spectroscopy is a nondestructive, highly specific sample analysis technique, which can be used to analyze low volume samples within seconds. Typically with SERS, one can increase Raman intensity by $10^{14\text{-}15}$ enhancement factors. Techniques such as SERS can be adopted for field use, as handheld Raman spectrophotometers are readily available in the commercial marketplace.

Laura Ricles, Ph.D.

Center for Biologics Evaluation and Research (CBER)

Preceptor: Steven Oh, Ph.D. (CBER)

Scientific & Professional Background

2009-2014 Ph.D. Biomedical Engineering, The University of Texas at Austin

2005-2009 B.S. Bioengineering, Lehigh University

Research Interests

Dr. Ricles' research background lies in cardiovascular tissue engineering, nanotechnology, and adult stem cells and their use in regenerative medicine. Her doctoral research investigated the use of bone marrow derived mesenchymal stem cell therapy, in combination with 3D biomaterials, for ischemic diseases. Specifically, she developed a gold nanoparticle system to label and monitor cells following delivery *in vivo* using combined ultrasound/photoacoustic imaging. In addition, she used *in vitro* models to elucidate the immunomodulatory effects of stem cells on macrophages, specifically pertaining to the process of angiogenesis and tissue repair. She also investigated the therapeutic benefits of stem cell therapy, including revascularization and functional recovery of tissue, following delivery within PEGylated fibrin gel into an *in vivo* ischemia model.

CFP Project Summary

Project Title: *Evaluation of Additive Manufactured Products: Current scientific trends, regulatory challenges, and enhancement of FDA review*

FDA Regulatory Science Priority Area: Ensure FDA Readiness to Evaluate Innovative Emerging Technologies

Additive manufacturing, or 3D printing, is driving innovations in many areas, including in the field of biologics. For example, technology is now available which is capable of printing more intricate geometries and features, personalized devices, and also incorporating live cells. With the incorporation of live cells, 3D printing can be used to print tissue engineered constructs or whole organs, which would help to address the issue of the limited supply of donor organs. However, the newness of this manufacturing capability raises potential technical and scientific issues which may impact product safety. As a result, a rigorous investigation of 3D printing technologies and 3D printed products would be of value. Therefore, this project aims to assist the FDA with evaluating 3D printed biologic products and providing regulatory guidance to stakeholders in developing safe and effective 3D printed biologic products for treating human diseases and conditions.

Silvia Secelean, Ph.D.

Office of Regulatory Affairs (ORA)

Preceptor: Donna Williams-Hill, Ph.D.

Scientific & Professional Background

2013 Ph.D. Public Health-Epidemiology, Walden University

1989 B.S. and M.S. Polytechnic Institute of Bucharest

Research Interests

- Epidemiology of emerging diseases
- Drug resistance and the threat to population health
- The role of novel cardiac markers in prediction and treatment of cardiac diseases
- Molecular biology and the impact on public health research
- FDA regulatory process in delivering drugs and biologics to humans

CFP Project Summary

Project Title: *Sequencing Mycobacterial Strains Isolated from Tattoo Inks*

FDA Scientific Priority Area: Harness Diverse Data through Information Sciences to Improve Health Outcomes

Detection of pathogens is essential for FDA regulatory requirements to protect public health, as well as for surveillance, diagnosis, and treatment. Tattoo related skin infections were recently reported in the United States. The CDC and FDA conducted investigations and determined that the pathogen associated with tattoo-related skin infections was Non-tuberculosis Mycobacterium (NTM) found in water and inks. Because tattooing became increasingly popular, in the effort to prevent the spread of tattoo-associated infections, FDA conducted investigations to determine the source of contamination. Traditional methods of identification, such as rate of growth, colony morphology, and biochemical profiles, as well as the newer molecular biology techniques, do not provide all data for particular level of discrimination and identification of the NTM strains. The main goal of this study is to utilize the Whole Genome Sequencing to develop a database that would assist in definitively identifying mycobacterial isolates and provide molecular evidence in epidemiological studies.

Eric L Stevens, Ph.D.

Center for Food Safety and Applied Nutrition (CFSAN)

Division of Microbiology

Preceptor: Peter Evans, Ph.D., M.P.H.

Scientific & Professional Background

2013 - 2014	Postdoctoral Fellow, Department of Psychiatry and Behavioral Sciences Johns Hopkins School of Medicine
2013	Ph.D. Human Genetics and Molecular Biology Johns Hopkins School of Medicine
2008	B.S. Biotechnology Rochester Institute of Technology

Research Interests

Eric's research interests have focused on the estimation of genetic relatedness among individuals and its application towards large, population-based datasets. During his graduate studies, he came up with a novel method to infer genetic relationships using identity-by-state and identity-by-descent. Additionally, he developed novel methods for detecting small regions of homozygosity in a child due to consanguinity between the parents. Finally, he generated methodologies to reconstruct human pedigrees using gen otype data. His postdoctoral experience aimed at using RNA sequencing analysis to compare the transcriptomes of individuals with schizophrenia with controls. He has an overall interest in sequencing technology and its many uses from identifying causative-mutations to the source attribution of food-borne pathogens.

CFP Project Summary

Project Title: *The role of Whole Genome Sequencing (WGS) in foodborne illness source attribution and its impact on regulatory science*

FDA Scientific Priority Area: Implement a New Prevention-Based Food Safety System to Protect Public Health

In 2011, the FDA along with the CDC and USDA created the Interagency Food Safety Analytics Collaboration (IFSAC). IFSAC's goal is to improve The Federal Food Safety System through coordinated source attribution efforts by various federal agencies. This was in response to the passage of the Food Safety and Modernization Act put into law in 2011. WGS allows clusters of clinical isolates to be grouped and linked to the environmental/food source with unparalleled sensitivity and specificity. It has been previously demonstrated that using WGS methodologies for foodborne pathogens has successfully linked outbreaks and attributed them to a common source. This will provide a better understanding of the effect regulatory prevention measures has on reducing foodborne illnesses.

Peter Tobin, Ph.D.

Division of Program Operations and Management
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health (CDRH)

Preceptor: Brendan O'Leary

Scientific & Professional Background

2011-2014 Ph.D. Engineering & Applied Science, Yale University

2008-2011 M.S., M.Phil. Engineering & Applied Science, Yale University

2004-2008 B.S. Materials Science & Engineering, Cornell University

Research Interests

Peter's research interests span biotechnology, process engineering, economics, and regulatory science. His graduate research focused on leveraging computational protein design to engineer proteins for energy and electron transfer. Peter's current research interests include quality management for service and regulatory organizations, regulatory science process engineering, regulatory science metrology, and risk management.

CFP Project Summary

Project Title: *Development of a Quality Management System for the Office of In Vitro Diagnostics and Radiological Health*

Regulatory Science Priority Area: Ensure FDA Readiness to Evaluate Innovative Emerging Technologies

Quality Management Systems (QMSs) are a set of customer and systems focused management techniques that have been used successfully in both manufacturing and service organizations to continuously improve product quality and consistency since the 1950's. Additionally, QMSs are an important aspect of regulatory science integral to FDA current good manufacturing practices regulation for food, drugs, biologics, and devices. This project encompasses helping to develop a QMS for the Office of In Vitro Diagnostics and Radiological Health (OIR) in order to facilitate regulatory process improvement and improve the consistency of regulatory decision making. The specific aims of this project are: (1) Complete a systematic review of the design and implementation of QMSs for regulatory agencies, (2) Develop and baseline quality metrics for selected OIR programs, and (3) Implement a QMS for selected OIR programs including a corrective and preventative action (CAPA) system and development of a resource management plan to ensure that current and new employees can find and effectively use IT, training, and policy resources.

Todd Townsend, Ph.D.

National Center for Toxicological Research (NCTR)
Division of Genetic and Molecular Toxicology
Preceptor: Mugimane (Manju) Manjanatha, Ph.D.

Scientific & Professional Background

Education:

2008: Ph.D., Pharmacology; Vanderbilt University
2003: B.S., Human Biology; Michigan State University

Experience:

2008 – 2014: Postdoctoral Fellow; University of Utah, Molecular Medicine Program
2012 – 2014: NHLBI Individual Postdoctoral Fellow, Grant F32HL114181
2009 – 2011: American Heart Association Individual Postdoctoral Fellow, Grant 09POST2260423
2008: Postdoctoral Fellow; Vanderbilt University, Department of Pharmacology
2003 – 2008: Graduate Research Fellow; Vanderbilt University, Department of Pharmacology

Research Interests:

Todd is interested in the development and implementation of rapid, cost-effective techniques to assay drug safety and toxicology, with a particular interest in compounds causing epigenetic modifications. Todd's previous research has focused on two areas. The first was the development of tools to isolate cell signaling pathway-, temporal-, and lineage-specific information using genome wide association studies in zebrafish. The second focus was on TGFβ signaling in several model systems, with an emphasis on cardiac development and the regulation of EMT.

CFP Project Summary

Project Title: *Modification of the Comet Assay for in vitro and in vivo Assessment of the Global DNA Methylation Status*

FDA Regulatory Science Priority Area: Modernize Toxicology to Enhance Product Safety

The laboratory has recently established the standard alkaline single cell gel electrophoresis (Comet) assay to assess DNA damage produced by chemicals relevant to the FDA. This assay is a sensitive, simple and cost-effective technique for analyzing and quantifying a broad spectrum of DNA damage in individual cells induced by genotoxic chemicals. Importantly, this assay is amenable to modification to allow for the measurement other endpoints, such as oxidative DNA damage, which appears to be the genotoxic mode of action for carcinogenicity of many chemicals. Considering the important role of epigenetic mechanisms such as DNA methylation in carcinogenesis, we will adapt the enzyme-modified Comet assay approach to assess global methylation status in individual cells. The development of this sensitive and fast method to measure DNA methylation in individual cells, isolated from distinct tissues, will be highly informative for human risk assessment of FDA relevant drugs or pharmaceuticals.

Xia Xu, Ph.D.

Office of Regulatory Affairs

Northeast Regional Laboratory

Preceptor: Paul M. Morin, Sc.D.

Scientific & Professional Background

2007-2014 **Ph.D. Microbiology and Immunology, Albert Einstein College of Medicine, Yeshiva University**

2005-2007 **Research Assistant, NIAID/National Institutes of Health**

2003-2004 **Medical Technologist, Huashan Hospital, Fudan University, China**

2000-2003 **M.S. Laboratory Medicine, Sichuan University, China**

1995-2000 **B.S. Laboratory Medicine, Sichuan University, China**

Research Interests

Xia's main research interests are in infectious diseases. Her previous research focused on *Mycobacterium tuberculosis*, the causative agent of human tuberculosis disease. She was particularly interested in pathogenesis, drug resistance and novel drug target identification. Her thesis studies revealed the important roles of mycothiol biosynthesis in both the pathogenesis and antitubercular drug susceptibilities of *M. tuberculosis*.

CFP Project Summary

Project Title: *Application of next generation sequencing in subtyping Listeria monocytogenes and comparison with pulsed-field gel electrophoresis*

FDA Regulatory Science Priority Area: Ensure FDA Readiness to Evaluate Innovative Emerging Technologies

Next generation sequencing (NGS) is a new emerging technology that allows concurrent high-throughput parallel sequencing by using the sequencing-by-synthesis technique. Today, this cutting-edge technology has evolved to an ultra-high throughput and low cost analysis. NGS is increasingly applied to broad areas ranging from genome, epigenome, metagenome to whole transcriptome and drug development. This project aims to evaluate whether NGS can be a preferred molecular subtyping tool for foodborne pathogens such as *Listeria monocytogenes* in a regulatory laboratory. *L. monocytogenes* is a life-threatening foodborne pathogen which leads to high hospitalization and mortality rates during Listeriosis outbreaks. Pulsed-field gel electrophoresis (PFGE), the current standard subtyping method, can fail to distinguish unrelated strains because of its inability of providing genomic information at the single nucleotide level. This study will compare genetic data from NGS and PFGE to determine if NGS is a more powerful subtyping method that can be used for foodborne pathogen surveillance and outbreak investigations for regulatory purposes.

Jia Yao, Ph.D.

National Center for Toxicological Research (NCTR)

Preceptor: Yongbin Zhang, Ph.D.

Scientific & Professional Background

2011-2014	Senior Research Associate, University of Southern California
2010-2011	Postdoctoral Research Associate, University of Southern California
2005-2010	Doctor of Philosophy, Molecular Pharmacology and Toxicology, University of Southern California, USA
2008-2009	Master of Science, Regulatory Science, University of Southern California, USA
2002-2005	Master of Science, Biochemistry and Molecular Biology, Nanjing University, China
1998-2002	Bachelor of Science, Biochemistry, Nanjing University, China

Research Interests

Jia's previous research focuses on the "from bench to bedside" translation which includes understanding the pathogenic mechanisms of neurodegenerative diseases, identification of mitochondrial bioenergetics and neural stem cells as therapeutic targets, development of novel therapeutic candidates, and preclinical toxicity, safety as well as efficacy assessment.

CFP Project Summary

Project Title: *Mechanistic Toxicological Evaluation of Engineered Nanomaterial Using a Human Stem Cell Model*

FDA Regulatory Science Priority Area: Modernize Toxicology to Enhance Product Safety

Nano-materials have been widely used in consumer products regulated by FDA. FDA has developed nanotechnology regulatory science program to enhance nano-material characterization, *in vitro* and *in vivo* modeling and product-focused research. However, there is an unmet need for reliable, highly-predictive, and cost-effective assessment of the safety and toxicity of nano-materials. The regulatory objective of this research project is to establish a human stem cell model for nanotoxicity testing. The scientific objective of this project is to contribute to FDA's scientific understanding of the mechanisms of nanoparticle action by 1) evaluating the toxicity of different nano-materials in human induced pluripotent stem cell (hIPS) and human mesenchymal stem cell (hMSC) models; (2) determining the cellular uptake and distribution of nano-materials; and (3) investigating the mechanisms of nano-material induced alteration in cell differentiation in hIPS and hMSC models.

Shadia Zaman, Ph.D.

Office of Clinical Pharmacology

Center for Drug Evaluation and Research (CDER)

Preceptor: Darrell R. Abernethy, M.D., Ph.D.

Scientific & Professional Background

2013-2014	Instructor, Department of Experimental Therapeutics, The University of Texas MD Anderson Cancer Center
2011-2013	Postdoctoral Fellow, Department of Experimental Therapeutics, The University of Texas MD Anderson Cancer Center
2007-2011	Visiting Fellow, Metabolic Diseases Branch, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health
2001-2007	Ph.D. in Molecular Biology, Princeton University
1997-2001	B.A. in Molecular Biology and Biochemistry, Rutgers University

Research Interests

Dr. Zaman's research interest is in developing targeted anti-cancer drugs. As a postdoctoral fellow and instructor at MD Anderson, she investigated the mechanism of action and efficacy of novel small-molecule agents as anti-cancer therapy for hematologic malignancies. As a visiting fellow at National Institutes of Health, she studied how the tumor suppressor menin caused endocrine tumors. Her graduate research focused on dissecting the glucose signaling network by designing drug-sensitive kinase mutants that regulated glucose signaling pathways.

CFP Project Summary

Project Title: *Predicting cardiac adverse events associated with tyrosine kinase inhibitors*

FDA Regulatory Science Priority Area: Modernize Toxicology to Enhance Product Safety

A major public health concern in drug development is the associated adverse drug reactions. Tyrosine kinase inhibitors (TKIs) have been championed as molecularly targeted therapies; however, some TKIs have adverse cardiovascular side effects including congestive heart failure and hypertension. The tyrosine kinases these drugs are targeted to are expressed not only in tumor tissue, the desired target, but also other tissues and organs, including the heart. To understand and predict cardiovascular risk for these drugs, a systems pharmacology network is being constructed to relate the molecular targets to observed clinical congestive heart failure. An ontology is being constructed (Ontology of Adverse Events) to establish relations between the various levels of biological function (molecular, biochemical pathway, organs, etc) to the clinical syndrome. This will support the development of a computational system for prediction of TKI-induced congestive heart failure. As pharmaceutical companies develop new drugs in this class, this predictive network will be critical to understand each drug candidate's cardiovascular risk.

FDA Commissioner's Fellowship Program

2014 Preceptors

Darrell R. Abernethy, M.D., Ph.D.

Associate Director for Drug Safety

Office of Clinical Pharmacology/OTS/CDER/FDA

Background:

M.D., Ph.D. (Pharmacology)

4 years FDA experience

8 years NIH experience

18 years academic experience

Research Interests:

1. Mechanism based predictive drug safety
2. Systems Pharmacology applied to drug safety
3. Integration of bioinformatics tools for predictive drug safety

Marli Azevedo, M.S., Ph.D.

Division of Microbiology

National Center for Toxicological Research

3900 NCTR rd, Jefferson, AR 72079

Background:

Ph.D. - Virus Immunology, The Ohio State University, USA

Post-doctoral fellow - Virus Immunology, The Ohio State University, USA

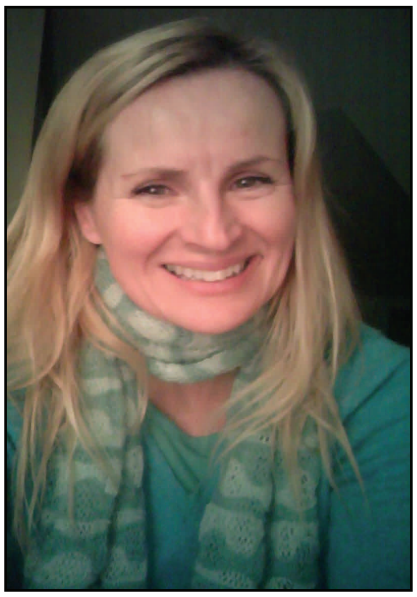
Academic Positions - Research Scientist and Adjunct Assistant Professor, The Ohio State University

FDA Experience - 4 years

Research Interests:

Our current studies are focused on respiratory and enteric viruses, among them: Coronaviruses and Noroviruses. Coronaviruses are responsible for causing acute respiratory tract infections in humans and respiratory, gastrointestinal, neuropathies and systemic diseases in animals. Noroviruses are responsible for 60% of the food and waterborne gastroenteritis outbreaks. Twenty-three million Americans are sickened with Norovirus yearly, accounting for 50,000 hospitalizations and 300 deaths.

We have used qRT-PCR, RT-PCR, plaque assay, virus isolation, cloning, sequencing, confocal microscopy, immunofluorescence assay and cell culture, among other techniques, to study the mechanism of transmission of coronavirus and to determine the current strains circulating in humans and animals in Arkansas. We have identified a feline and a canine norovirus circulating in Arkansas. We have also constructed a norovirus-like particle to assess the exposure to canine or feline norovirus by humans. We are currently exploring a cell culture model to support norovirus replication.



Nicolette Borek, Ph.D.

Office of Science

Center for Tobacco Products/FDA

Background:

Nicolette Borek is a Clinical Psychologist in the Office of Science, Center for Tobacco Products. She has worked with FDA for over two years as a member of the Addiction Team and the PATH Study management team. Dr.Borek joined FDA after working at the National Institutes of Health, National Institute on Drug Abuse (2002-2012) and National Institute of Mental Health (2000-2002).

Research Interests:

Clinical research including the development of nicotine addiction and dependence, youth tobacco initiation, and consequences of exposure to tobacco during development.

Peter Evans, Ph. D, M.P.H.

Supervisory Microbiologist

FDA CFSAN Office of Regulatory Science

Division of Microbiology

Chief, Molecular Methods and Subtyping Branch (MMSB)

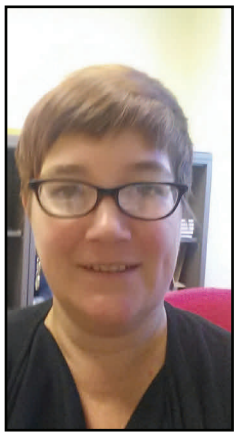
Background:

FDA CFSAN 2012 - present

USDA's Food Safety Inspection Service 2005 – 2012

Research Interests:

Commercially-available benchtop next generation sequencing (NGS) instruments based on novel and robust chemistries have been developed by the private sector [1] and are being used to collect the complete genomic content of bacterial pathogens (typically 3—5 million base pairs) within one to two days at a cost of U.S. $150 or less from a microbiologically-pure isolate and instrumentation costing U.S. $100,000 or less. These price points are making NGS instruments accessible beyond specialized sequencing facilities. In the very near future, NGS instruments will be accessible to clinical and food microbiology labs serving the private and public health sector and public health functions, including outbreak cluster detection, traceback investigations and source attribution studies. MMSB is actively exploring this future with a pilot project that is evaluating the utility of a distributed network of benchtop NGS instruments to create a publically accessible database of *Salmonella* genomes with rich sample data. The Genometrakr database currently contains over 1,500 genomes submitted by six state public health labs, nine FDA regulatory public health labs, and one commercial food testing lab. MMSB is seeking to extend the network to include one or more sites in economically developing countries (in collaboration with the World Health Organization) and to evaluate the utility of real time data for outbreak cluster investigation and traceback (in collaboration with the U.S. Centers for Disease Control). The importance of NGS networks has been recognized by FDA and internationally [Aarestrup et al., 2012].



Suzanne Hill

CFSAN/OFAS

Background:

Supervisory Biologist, FDA, 2 months, Environmental Team Supervisor

General Services Administration, 7 years, Regional Environmental Planning Officer

BS, Watershed Science, Utah State University

MA, Science Education, Columbia University

Research Interests:

In general my role at FDA is as the environmental team supervisor in Office of Food Additive Safety in CFSAN. My role is primarily ensuring that CFSAN conducts environmental reviews in accordance with the National Environmental Policy Act, and NEPA implementing regulations. The environmental review team evaluates pre-market approvals for potential environmental impacts. We also provide environmental review of CFSAN rules.

Research that we conduct is relevant to food contact substances and their environmental impact, including toxicity to aquatic organisms and terrestrial organisms. We also are concerned with air quality impacts that may occur from the combustion of materials that include the FCS, recently we have begun researching potential issues related to combustion in municipal solid waste and possible greenhouse gas emissions.

Sean W. Linder, Ph.D.

Arkansas Regional Laboratory (ARL)

National Center for Toxicological Research (NCTR)

Background:

Ph. D. - Analytical Chemistry, University of Arkansas

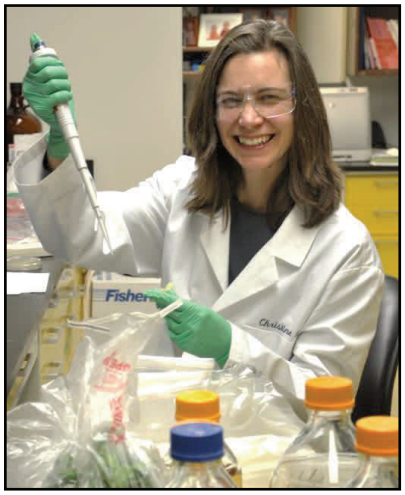
B. S. - Chemistry, Henderson State University

FDA Experience - 5 Years

Research Interests:

Our research is at the interface of materials chemistry, analytical chemistry, and nanotechnology. The team's primary goal is to develop methodologies to identify and characterize nanoscale materials (metallic, metal oxide, liposomal, polymeric, and silica nanoparticles) in FDA regulated products. A diverse range of projects are currently pursued in the group:

1. Application of x-ray fluorescence (XRF) spectroscopy as a screening tool for nanoscale materials in FDA regulated products
2. Development of regulatory methods for the characterization of nanoscale metal oxides in sunscreens, dietary supplements, and feminine hygiene products
3. Development and application of liquid chromatography/mass spectrometry techniques for the characterization and identification of liposomal nanoparticles within FDA regulated products
4. Development of hyphenated size-based separation techniques (e.g., asymmetric field flow fractionation, capillary electrophoresis, liquid chromatography) using inductively coupled plasma/mass spectrometry (ICP/MS)
5. Development of methods to detect toxic elements in nano-based dietary supplements using ICP/MS



Christine Karbiwnyk, Ph.D.

Winchester Engineering and Analytical Center, ORA

Winchester, MA

Background:

B.S. Chemistry, University of New Haven

B.S. Forensic Science, University of New Haven

Ph.D. Analytical Chemistry, University of Colorado-Boulder

FDA experience 12 years

Research Interests: Applying new technologies to chemistry and microbiology regulatory analysis.

Mugimane (Manju) Manjanatha, Ph.D.

Division of Genetic and Molecular Toxicology,

National Center for Toxicological Research
Jefferson, AR

Background

B.Sc-India

M.S.- West Texas A&M

Ph.D.- Iowa State University

FDA Experience – 20 Years, mentored 4 postdocs and 8 summer students

Research Interests

Modification and utilization of the single cell gel electrophoresis assay (Comet assay) for the assessment of genotoxic and epigenetic modes of action of FDA regulated agents for cancer induction; development and use of transgenic rodents with reporter genes for hazard identification and characterization.

Paul M. Morin, Sc.D.

Northeast Regional Laboratory/ORA

Background:

1989 B.S. University of Vermont

1998 Sc.D. Harvard School of Public Health

1998-2002 Postdoctoral Fellow, Albert Einstein College of Medicine

2003-Present FDA Microbiologist

Research Interests:

1. Next Generation Sequencing
2. Real Time PCR for the detection of foodborne pathogens
3. Method development and validation for high risk pathogens involving select agents
4. Biosafety Level 3 procedures and practices involving food security and food defense

Steven S. Oh, Ph.D.

Acting Chief, Cell Therapies Branch

Office of Cellular, Tissue and Gene Therapies

Center for Biologics Evaluation and Research

Background:

Ph.D., University of Michigan

Postdoctoral Fellowship: Johns Hopkins University School of Medicine & Massachusetts Institute of Technology

Faculty, Tufts University School of Medicine

FDA Experience – Since 2007

Research Interests:

Dr. Oh serves as Acting Chief of Cell Therapies Branch. His areas of scientific and regulatory interests are focused on cellular products, tissue-engineered products, device-biologic combination products, and certain medical devices having regenerative or therapeutic indications. He provides leadership in reaching various regulatory decisions on medical products submitted to CBER for marketing, clinical investigation, or classification. He also actively participates in policy development and staff training for cell-based innovative products. His unique experience in CBER and CDRH has been crucial to Dr. Oh's appreciation of balanced approaches to biologic and device scientific reviews and regulatory oversights. Dr. Oh founded and led Device Biologics Interest Group which provides a forum for the FDA regulatory staff to cross-train and exchange new ideas that are applicable to cellular and tissue-engineered products. He continues in his efforts to harmonize scientific review practices and standards for cellular and tissue-engineered products, combination products and related devices regulated by the Agency.

Brendan O'Leary

Policy Analyst

Division of Program Operations and Management

Office of In Vitro Diagnostics and Radiological Health

Center for Devices and Radiological Health

10903 New Hampshire Ave

Silver Spring MD 20993-0002

Background:

BS in Mechanical Engineering

5 years of employment at FDA reviewing premarket submissions, consulting on postmarket activities, developing and implementing policies, and evaluating regulatory science priorities.

Research Interests:

Quality management systems

Radiological health

Diagnostic devices

Zuben E. Sauna, Ph.D.

Laboratory of Hemostasis,

Division of Hematology,

Office of Blood Research and Review

Center for Biologics Evaluation and Research (CBER)

Background:

B.Sc. Ed. Bhopal University, India

M.Sc. Poona University, India

Ph.D. Poona University, India

YEARS AT FDA: 5

Research Interests:

The development of neutralizing anti-drug antibodies (nADAs) to therapeutic-proteins can adversely affect the efficacy and safety of these drugs. There are also racial/ethnic disparities. For instance, in the treatment of hemophilia-A; prevalence of nADAs to the therapeutic protein (Factor-VIII) among African Americans is about twice that in Caucasians. Our recent work suggests that non-synonymous single nucleotide polymorphisms (ns-SNPs) in the endogenous (albeit nonfunctional) *F8* could present risk-factors for the development of nADAs. By using an immunogenicity score we have developed we show that mutations, nsSNPs in the endogenous *F8* gene and the HLA type may be biomarkers that explain the higher incidence of immunogenicity in African Americans. The methods we develop could have uses that go beyond race-based determinants of immunogenicity. For example, second- and third-generation therapeutic-proteins, which have been engineered to improve product attributes or to enhance process characteristics, are rapidly becoming the norm. Immunogenicity is a serious concern because engineered proteins include mutations, deletions and the introduction of linkers, junctions and fused polypeptides not normally found in nature and thus can potentially elicit immune responses. The computational, *in vitro* and *ex vivo* methods developed in our laboratory can raise red-flags early during the development process and also guide the planning of Phase III clinical trials. We are currently applying our methods to understand whether neo-epitopes generated during the design of two new Factor-VIIa analogs may have made them mmunogenic. These two products were discontinued in Phase III trials due to mmunogenicity in some (though not all) patients. If we can validate our approaches such individuals could be potentially identified in early stages of drug development opening the door to clinical trials based on pharmacogenetics. The major advantage of such an approach is that drugs such as these, which are highly beneficial and pose little or no risk to a great many patients, could be developed with a co-diagnostic that could identify individuals for who the drug is unsuitable

Irshad Sulaiman, M.Sc., M.Phil, Ph.D.

Microbiological Sciences Branch
Southeast Regional Laboratory (SRL)
Office of regulatory Affairs (ORA)

Background:

Ph.D. – University of Delhi, India
M.Phil. – A. M. University, India
M.Sc. – A. M. University, India

FDA Experience – 4 and half years (2008-Present

Professional Experience:

2011-Present: Adjunct Professor, Department of Biology, Georgia State University, Atlanta, Georgia
2008-Present: Research Microbiologist, Southeast Regional Laboratory, FDA, Atlanta, Georgia
2003-2008: Research Scientist, Division of Scientific Resources, CDC, Atlanta, Georgia
1997-2003: Visiting Scientist, Division of Parasitic Diseases, CDC, Atlanta, Georgia
1996-1997: Research Fellow, Medical College of Georgia, Augusta, Georgia
1993-1996: Young Scientist, National Institute of Immunology, New Delhi

Research Interests:

Dr. Sulaiman joined the Microbiological Sciences Branch, Southeast Regional Laboratory, U. S. Food and Drug Administration, Atlanta, Georgia as a Research Microbiologist on October 12th of 2008, with over 16 years of research experience and expertise in the field of molecular genetics and its application in method development to detect and differentiate various human-pathogenic emerging infectious agents. Before coming to FDA, Dr. Sulaiman worked at the Centers for Disease Control (CDC) for eleven and half years from 1997 to 2008. Dr. Sulaiman obtained his PhD degree in 1992 to study Conservation Biology, Population Genetics and Ecology of Endangered Species from University of Delhi.

Dr. Sulaiman's research for over 20 years has focused on the molecular genetic characterization and rapid detection methods for human-pathogenic parasites (Cyclospora, Cryptosporidium, Giardia), bacteria (Cronobacter, Bacillus, Salmonella), viruses (orthopox, SARS, Hepatitis A), fungi (Microsporidia, Indicator fungal species from environmental swabs), and some pest species (the FDA "Dirty 22" species) responsible for the spreading of foodborne pathogens, from outbreak settings, routine surveillance and sporadic cases for their Detection, Prevalence, Epidemiology, Transmission Dynamics, Taxonomy, Phylogeny and Evolutionary Relationships of public health importance.

Dr. Sulaiman has published over 70 manuscripts in peer-reviewed journals with high impact factors, and written 4 book chapters in his area of expertise.

Ram C. Tiwari, Ph.D.

Associate Director, Office of Biostatistics
Center for Drug Evaluation & Research (CDER)

Background:

M.S. & Ph.D. (Mathematical Statistics), Florida State University

Fellow, American Statistical Association

Member, International Statistical Institute

Previous Employment: Mathematical Statistician and Program Director, Surveillance Research program, NCI/NIH (2000-2008); Professor & Chairman, Department of Mathematics, University of North Carolina, Charlotte, NC (1994-2000); Asst./Assoc./Professor, Department of Mathematics, University of North Carolina, Charlotte, NC (1986-1994); Asst. Professor, Indian Institute of Technology, Bombay (2002-2006); Visiting Lecturer, UC Santa Barbara (1981-1982, 1985-1986).

Research Interests: i) Bayesian approaches for clinical trials; ii) signal detection in drug safety surveillance; and iii) meta-analysis

Donna Williams-Hill, Ph.D.

ORA/PAR, Pacific Regional Laboratory Southwest

Background:

1975, B.S. Biology, *magna cum laude*, Chemistry Minor Northern Illinois University, DeKalb,

1980, M.S. Biology, Illinois Institute of Technology, Chicago, IL.

1992, Ph.D. Microbiology, University of Southern California, Los Angeles, CA.

1992-1995, Post-doctoral Fellow Department of Human Oncology, University of Wisconsin, Madison, WI.

FDA Employee: 12/31/2000

Research Interests:

Projects center on the development of molecular methods to detect pathogens in foods:

1. Detection of pathogens utilizing Bio-Plex and Microarray technologies.
2. Use of Whole Genome Sequencing to characterize food and cosmetic pathogens.

Yongbin Zhang, D.V.M., Ph.D.

NCTR/ORA Nanotechnology Core Facility
Office of Scientific Coordination
National Center for Toxicological Research
Food and Drug Administration
Jefferson, AR 72079

Background:

Ph.D., Toxicology, Oklahoma State University
D.V.M., China Agricultural University
FDA experiences: 4 years

Research Interests:

- Toxicity, particle-kinetics and dermal penetration of engineered nanomaterials
- Confocal Raman Spectroscopy in nanotechnology and biomedical applications
- Alternative methods for toxicity testing of nano-products regulated by FDA
- Neurotoxicology of chemicals
- Regulatory science.